1743

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
YOSHIHIKO HIGUCHI, ET AL.	)	Art Group: **1743**
	)	
Serial No.: **09/473,165**	)	Examiner: **L. CROSS**
	)	
Filed: **December 28, 1999**	)	
	)	
For: **DRY MEASURING TEST DEVICE**	)	

SECOND RESPONSE TO OFFICE ACTION

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Responsive to the Office Action dated September 11, 2001 in the patent application identified above, please reconsider that application in view of the following remarks.

A Request for Extension of Time is submitted with this response.

REMARKS

Claims 6-8 and 10-13 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Arai et al. (U.S. Patent No. 5,589,347).

With the previous response, a declaration under 37 C.F.R. 1.132 showing unexpected advantages of embedding the light blocking particles in polymer beads over dispersing the light blocking particles into the polymer was submitted.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on **January 11, 2002**

Roger T. Frost - Reg. No. 22,176

However, the Examiner has stated that the declaration fails to show any substantial unexpected results. The Examiner stated as follows:

> "Applicant's evidence shows a difference of only a few seconds in using light blocking particles dispersed in a polymer (Arai et al '347) as opposed to light blocking particles embedded in a polymer. With respect to the hematocrit values, Applicants have argued that a lower influence of hematocrit values on reflectance results where embedded particles are used. Again, the difference in influences, as shown by the third graph in Applicant's declaration, is quite small."

The Examiner seems to underestimate the significance of the difference shown in the declaration, as discussed below.

As discussed in the previous response, the declaration shows that the measurement can be shortened. The difference is not a few seconds.

For the Examiner's reference, a new graph which is reproduced from the data shown in the declaration, is attached (Attachment 1). In Attachment 1, data at Ht (hematocrit value) of 45% which is considered as a normal value are overlaid for facilitating the comparison. "CB" is a prior art device as disclosed by Arai et al. "MBX-5/Black" is the device according to the present invention. The reflectance at 20 seconds when the device according to the present invention is used is the same as that at 40 seconds when the prior-art device is used. In other words, 20 to 30 seconds after the detection is started, the measurement can be completed in the case of the device according to the present invention, while reaction still progresses in the case of the prior-art device.

The dry measuring test device is generally used for screening because of its simplicity. A large number of specimens are usually tested by the dry measuring test device. In this case, it is clear how halving the required measurement time contributes to improvement of working performance. The Examiner fails to sufficiently consider what is desired by experts in this art. Reducing the 40-sec period to the 20-sec period (a 50% reduction) is remarkably significant in this art.

In the art of dry measuring test devices, there were many technological innovations to shorten the required measurement time. The shortening of the measurement time is the major problem in the development of dry measuring test devices. In fact, every time a manufacturer develops a new product, the required measurement time is shortened. Under these circumstances, halving of the measurement time achieved by the present invention is a remarkable and unexpected advantage. The Examiner's statement that the difference is only a few seconds is unreasonable in view of the nature of the art.

Also, tests using the dry measuring test device are used as "Point of Care" tests which are conducted at the patient's bedside. In this case, it is quite sure that the fact that the measurement is completed in half the usual time (that is, results are obtained more rapidly) compared with the prior art, remarkably relieves an inpatient from anxiety and stress. The shortening of the measurement time will result in shortening of the hospitalization period.

In addition, the shortening the measurement time contributes to improvement of accuracy and sensitivity of the measurement as discussed below.

As seen from the graph of the dry measuring test device shown in Attachment 1, in the time course of the prior-art dry measuring test device (CB), the point at which the curve begins to level is 60 seconds after the start of detection. This means that reaction between a reagent and a sample is substantially complemented after 60 seconds.

On the other hand, in the time course of the dry measuring test device of the present invention (MBX-5/Black), the point at which the curve begins to level is 30 seconds after the start of detection. This mean that reaction between a reagent and a sample is substantially completed after 30 seconds.

If the measurement is based on the end-point method, no result can be obtained before the completion of the reaction. That is, measurement can not be made before the completion of the reaction. In this connection, the shorter is the measurement time, the lesser is dryness of a sample. This is very advantageous feature in the dry measuring test device. In the case of the dry measuring tests device on which a small amount (e.g., one drop) of a sample is often provided, the measurement accuracy is largely affected by dryness caused by the difference of tens of seconds. See page 3, line 14 to page 4, line 1 of the present specification. The difference in tens of seconds is not negligible.

By using polymer beads embedding carbon black, the penetration rate of a sample is improved. That is, the development of the sample rapidly occurs in both the

vertical direction and the horizontal direction. Thus, the development of the sample is efficiently conducted. Because reaction between a reagent and a sample uniformly occurs by this feature, it becomes free from unevenness, which results in good accuracy. Also, the improvement of the penetration rate results in high sensitivity. If penetration of the sample is slow, the reaction between the reagent and the sample tends to be retarded. To the contrary, if penetration of the sample is fast, the sample is smoothly supplied to the reagent, whereby the reaction occurs under good conditions. Thus, high sensitivity is obtained.

As discussed above, the difference of tens of seconds is important and unexpected in the art.

Furthermore, as discussed in the previous response, the declaration shows that the influence of hematocrit values becomes small.

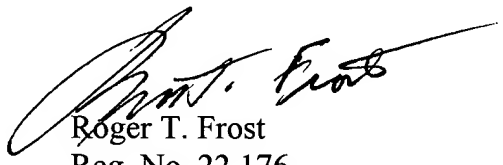
For further reference, a new graph which is reproduced from the data shown in the declaration, is attached (Attachment 2). In Attachment 2, the upper graph is the original graph in the declaration, and the lower graph is a graph reproduced by changing the Y axis from the reflectance to the glucose concentration. The concentration is calculated from the reflectance when the reaction is completed. That is, for calculation of the concentration, the reflectance at 40 seconds is used in the case of the prior art dry measuring test device (CB) and the reflectance at 20 seconds is used in the case of the dry measuring test of the present invention (MBX-5/Black). The standard curves for the calculation are shown in Attachment 3.

In the lower graph of Attachment 2, the Y axis is shown in the glucose concentration (mg/dl). As seen from this graph, the concentrations measured with the dry measuring test device of the present invention (MBX-5/Black) do not go out of the range of 150 to 200 mg/dl regardless of the hematocrit values. On the other hand, the concentrations measured with the prior-art dry measuring test device (CB) vary between 100 and 230 mg/dl because they are largely influenced by the hematocrit values. When the prior art dry measuring device is used, the measured blood sugar value may be different from the true valuably over 10 mg/dl. The measurement error is very significant in the clinical test for blood sugar.

The Examiner seems to underestimate the difference in the reflectance because how the clinical data is calculated from the reflectance is not considered. As discussed above, the difference in the reflectance shown in the declaration is significant in the art. The Examiner's statement that the difference is quite small is unreasonable in view of the nature of the art.

Based on the foregoing, the Applicants respectfully submit that the claimed device would not have been obvious to one of ordinary skill in view of Arai et al. Accordingly, the rejection on that reference should be withdrawn and a Notice of Allowance issued for this application. The Applicants respectfully request a Notice to that effect.

Respectfully submitted,



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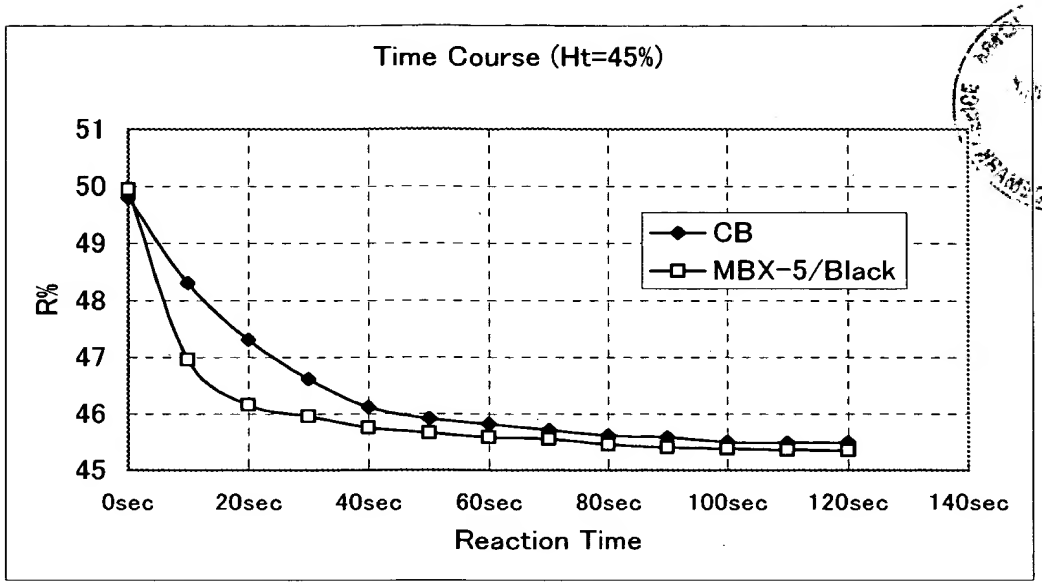
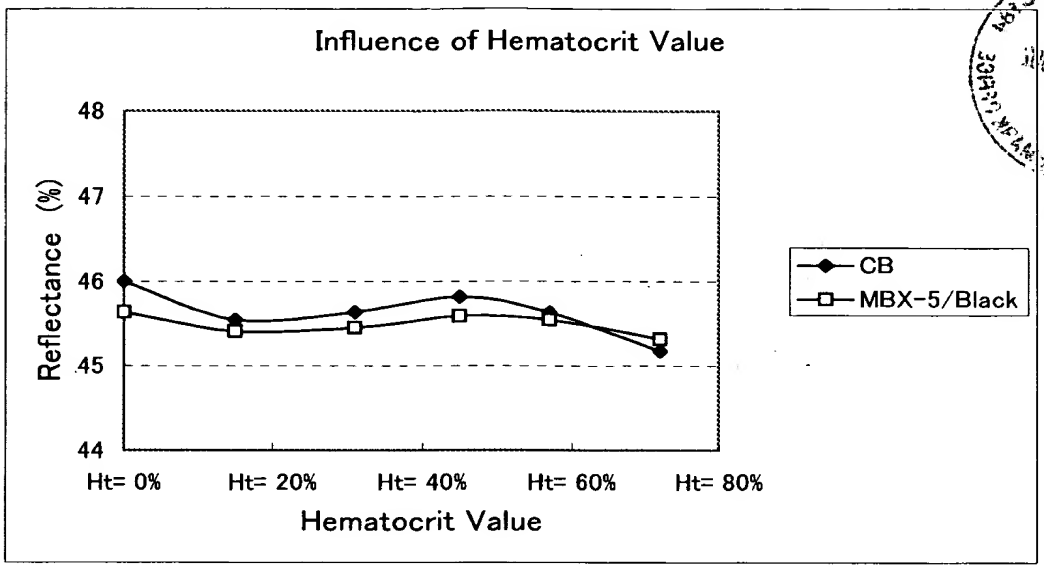
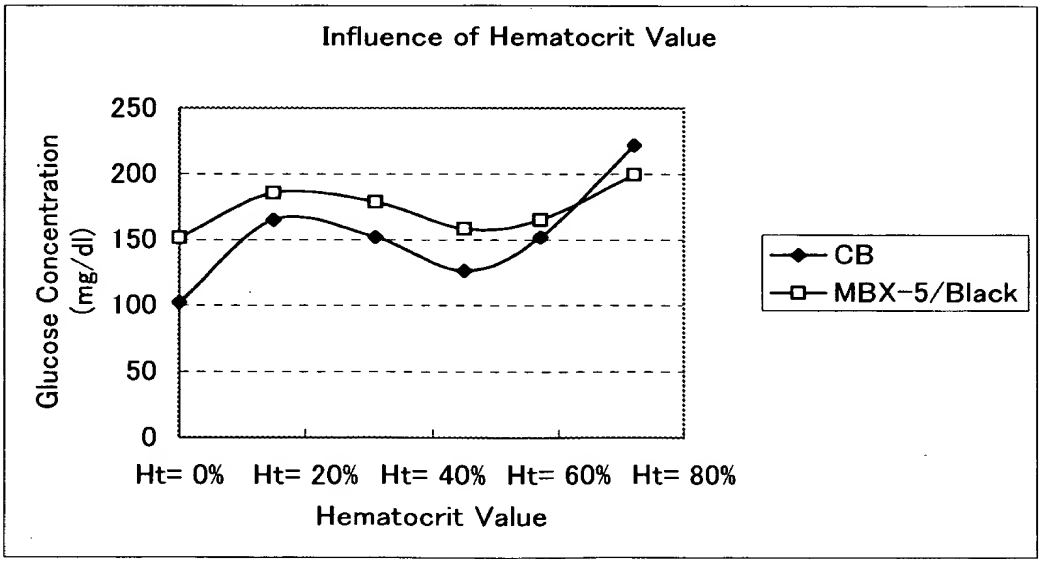
Attachment 1



Attachment 2





Attachement 3